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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,526	11/28/2003	Robert E. Arbogast	OHI 1717-006	8908
8698	7590	05/19/2006	EXAMINER	
STANDLEY LAW GROUP LLP 495 METRO PLACE SOUTH SUITE 210 DUBLIN, OH 43017			KASENGE, CHARLES R	
			ART UNIT	PAPER NUMBER
			2125	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/724,526	Applicant(s) ARBOGAST ET AL.	
	Examiner Charles R. Kasenge	Art Unit 2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-211 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 110-152 is/are allowed.
- 6) ☒ Claim(s) 1-72, 74-109, 153-186 and 192-211 is/are rejected.
- 7) ☒ Claim(s) 73 and 187-191 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed 2/28/06, with respect to the rejection(s) of the claim(s) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Watson et al. U.S. Patent 6,968,246, Haberman U.S. Patent 5,888,216, Pusch et al. U.S. Patent 6,383,148, Fay U.S. Patent 6,025,067 and Arbogast et al. U.S Patent Application 2003/0009354.

Claim Objections

2. Claim 73 is objected to because of the following informalities: the claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-7, 9-20, 22, 24-28, 30-41, 43, 45-53, 55-66, 68, 70-78, 80-91, 93, 95-109, 154-172, 174-186, 192-198 and 200-210 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. U.S. Patent 6,968,246 in view of Haberman U.S. Patent 5,888,216. Regarding claims 1, 22, 43, 48, 68, 73, 186, 192 and 193, Watson discloses a system for producing a custom prosthetic liner, comprising: a shape capture apparatus for capturing the

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3-dimensional shape of an amputee's residual limb (Fig. 3, 38 and col. 3, lines 18-24); a processing device for generating a 3-dimensional electronic liner model using said 3-dimensional shape captured by said shape capture apparatus (col. 5 and 6, lines 64-9), said processing device optionally adapted to generate a 3-dimensional electronic residual limb model (col. 3, lines 35-42); a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner (col. 5 and 6, lines 64-69);

Regarding claims 3-6, 24-27, 45-47, 49, 51, 52, 70-72, 74-77, 93, 95, 98, 99, 160-162, 168-171 and 194-197, Watson discloses the system of claim 1, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA) (Fig. 3, 42). Watson discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner (col. 5 and 6, lines 63-9). The Examiner interprets saving data on a floppy disk and sending it to the manufacturing facility as implicitly taught by Watson. Watson discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner (col. 5 and 6, lines 63-9). Watson discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said facility equipped to produce said custom liner over a local area

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network (LAN) or wireless local area network (WLAN) (col. 8, lines 52-67). The Examiner interprets transmission of data over the Internet to be inherent to computer data transmission. Tallarida et al. U.S. Patent 6,520,964 demonstrates this common form of data transmission (col. 16 and 17, lines 61-14).

Regarding claims 15, 16, 36, 37, 61, 62, 86, 87, 159, 163-167, 180 and 206, Watson discloses the system of claim 1, further comprising the ability to modify the shape of either or both of said 3-dimensional electronic models to accommodate particular features of said residual limb in said custom prosthetic liner (col. 4 and 5, lines 64-67 and 1-8). Watson discloses the system of claim 1, further comprising the ability to select liner materials and material properties (col. 4, lines 4-25).

Watson discloses using the model data to create the prosthetic liner, but does not go into detail about how the liner is produced in the manufacturing facility (col. 4, lines 58-67) and does not expressly disclose making the liner with a flexible polymeric material. Regarding claim 1 and correlating claims shown above, Haberman discloses an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both (col. 7 and 8, lines 60-16); a mold for receiving and containing an amount of said flexible polymeric material (col. 2, lines 57-61), said mold incorporating said at least one custom mold component; and a molding machine for producing said custom prosthetic liner from said mold (col. 8, lines 38-52). Regarding claims 7, 28, 53, 78 and 172, Haberman discloses at least one custom mold component is produced from said data by a computer-controlled machining device that utilizes numerical data (col. 7 and 8, lines 60-16).

Regarding claims 9-14 and correlating claims, Haberman discloses the system of claim 1, wherein said at least one custom mold component is a mold core for use with a common mold cavity (col. 7 and 8, lines 60-16). Haberman discloses the system of claim 9, wherein said mold cavity is selected based on its size (col. 7 and 8, lines 60-16). Haberman discloses the system of claim 1, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core (col. 7 and 8, lines 60-16). Haberman discloses the system of claim 1, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material (abstract). Haberman discloses the system of claim 12, wherein said custom prosthetic liner is manufactured from a block copolymer material (abstract). Haberman implicitly discloses the system of claim 1, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process (col. 1, lines 29-40).

Regarding claims 17-20 and correlating claims, Haberman discloses the system of claim 1, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner (col. 2, lines 50-52). Haberman discloses the system of claim 17, wherein the number, location, and orientation of said accessories may be specified (col. 2, lines 50-52). Haberman discloses the system of claim 17, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors (col. 2, lines 50-52). Haberman discloses the system of claim 18, wherein said additives include anti-microbial substances (col. 2, lines 53-56).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine Watson's prosthetic liner design and Haberman's manufacturing methods in order to produce the prosthetic liner. One of ordinary skill in the art would have been

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motivated to do this since Haberman teaches manufacturing a prosthetic liner from a CAD model (col. 7, lines 22-28 and col. 8, lines 38-52).

5. Claims 2, 23, 44, 69 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson and Haberman as applied to the claims above, and further in view of Pusch et al. U.S. Patent 6,383,148. Watson and Haberman do not disclose spaced-apart image detectors. Pusch discloses a plurality of spaced-apart image detectors that create a model (Fig. 1 and abstract).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art use Pusch's plurality of spaced-apart image detectors. One of ordinary skill in the art would have been motivated to do this since they allow for more accurate shape data (col. 1, lines 44-49).

6. Claims 8, 29, 54, 79, 173 and 199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson and Haberman as applied to the claims above, and further in view of Fay U.S. Patent 6,025,067. Watson and Haberman do not disclose the use of closed-cell foam material. Fay discloses a mold for a prosthetic liner created from a closed-cell foam material (col. 6, lines 54-67 and col. 8, lines 7-25).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use closed-cell foam material for a custom mold. One of ordinary skill in the art would have been motivated to do this since Fay discloses it as common in prosthetic liner fabrication (col. 6, lines 22-47).

7. Claims 21, 42, 67, 92, 153 and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson and Haberman as applied to the claims above, and further in view of Arbogast et al. U.S Patent Application 2003/0009354. Watson and Hagerman do not disclose a medical device purchasing system. Arbogast discloses an automated system for configuring and purchasing a medical device (abstract).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use the purchasing system for purchasing a prosthetic liner. One of ordinary skill in the art would have been motivated to do this since in order to improve practitioner purchasing flexibility (pg. 2, ¶17).

Allowable Subject Matter

8. Claims 110-152 are allowed.

9. Claims 187-191 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose a shape capture apparatus for capturing shape data of the interior of an existing prosthetic socket nor does the prior art disclose obtaining shape data from a cast. The allowability, at least in part, resides in these facts.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

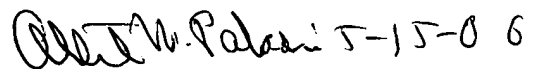
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles R. Kasenge whose telephone number is 571 272-3743. The examiner can normally be reached on Monday through Friday, 8:30 - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571 272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CK
May 11, 2006

 5-15-06

ALBERT W. PALADINI
PRIMARY EXAMINER